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PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Resources Administration

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NATIONAL GUIDELINES FOR HEALTH PLANNING

Advance Notice of Proposed Rulemaking

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[42 CFR Part 121]

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Advance Notice of Proposed Rulemaking

AGENCY: Public Health Service, HEW.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This Notice sets forth, pursuant to section 1501 of the Public Health Service Act, proposed National Guidelines for Health Planning with respect to the following types of health services and facilities:

General hospital beds,
Obstetrical inpatient services,
Pediatric inpatient services,
Neonatal intensive care units,
Open heart surgery units,
Cardiac catheterization units,
Radiation therapy,
Computed tomographic scanners,
End-stage renal disease.

The Notice invites all interested parties to submit written comments and recommendations concerning the proposed National Guidelines for Health Planning. After consideration of the material received in response to this Notice, the Secretary of Health, Education, and Welfare will by regulation issue final Guidelines on the specified health services and facilities.

DATE: Comments must be received by November 22, 1977.

ADDRESS: Written comments and recommendations should be submitted, preferably in duplicate, to: Office of Planning, Evaluation, and Legislation, Health Resources Administration, Center Bldg., Room 10-22, 3700 East-West Highway, Hyattsville, Maryland 20782. All materials received in response to this Notice and background material which has contributed to the development of the proposed National Guidelines will be available for public inspection and copying at the above location during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Daniel I. Zwick, Associate Administrator for Planning, Evaluation, and Legislation, Health Resources Administration, Center Bldg., Room 10-22, 3700 East-West Highway, Hyattsville, Maryland 20782 (301-436-7270).

SUPPLEMENTARY INFORMATION: Section 1501 of the Public Health Service Act, as amended by the National Health Planning and Resources Development Act of 1974 (Pub. L. 93-641), requires the Secretary of Health, Education, and Welfare to issue, by regulation, guidelines concerning national health planning policy. The guidelines are to include:

(1) Standards respecting the appropriate supply, distribution, and organization of health resources, and

(2) A statement of national health planning goals developed after consideration of the priorities set forth in section 1502, which goals, to the maximum extent practicable, shall be expressed in quantitative terms.

The purposes of the National Guidelines for Health Planning are to help clarify and coordinate national health policy and to assist Health Systems Agencies (HSAs) established pursuant to section 1512 of the Public Health Service Act in developing required Health Systems Plans.

In section 2 of Pub. L. 93-641 (42 U.S.C 300k; 88 Stat. 2226), entitled "Findings and Purpose", Congress stated that achievement of "equal access to quality health care at a reasonable cost is a priority of the Federal Government" (section 2(a)(1)). The Congressional findings also noted that increases in the cost of health care, particularly of hospital stays, have been uncontrollable and inflationary (section 2(a)(4)), and that public and private sector responses have not resulted in the restraint of costs (section 2(a)(3)). However, in addition to a concern over problems of cost, Pub. L. 93-641 also emphasized concern with access to services and quality of care. Set forth for priority consideration in the formulation of national health planning goals are, among other things, the provision of primary care services for medically underserved populations, especially those which are located in rural or economically depressed areas, and the promotion of activities to achieve needed improvements in the quality of health services (see section 1502 of the Public Health Service Act as amended by Pub. L. 93-641).

The National Guidelines for Health Planning, as their development proceeds, will encompass concerns of accessibility to services, quality of care, and the containment of costs. However, consistent with new Departmental initiatives attaching priority to the role and increased responsibilities of planning agencies in addressing the reduction of the rapid rate of inflation of health care costs, the focus of this initial issuance of the National Guidelines for Health Planning is on short-term opportunities for cost containment and quality enhancement in the institutional sector. There is documented evidence, for example, that the nation has an excessive supply of hospital beds, even recognizing that some areas have too few. The preponderance of health care services provided in acute care institutions, which have experienced the highest rate of inflation, has led to the belief that the principal cost savings are achievable in this area.

It has been demonstrated that cost savings can be achieved without sacrificing the quality of or access to care for underserved areas or population groups through more efficient utilization of existing resources. For example, it is clear that conversion of excess acute care hospital beds to more appropriate uses, or the closure of excess capacity, can conserve resources and thus provide an opportunity for opening access to the underserved and for improvements in the quality of care. Moreover, limitations of certain excess resources, such as the duplication of open-heart units, can lead to improvements in the quality of care, while at the same time containing costs.

The initial issuance of the National Guidelines focuses on certain institutional resources, the excess supplies of which need to be contained if the rapid escalation of health care costs is to be moderated. These Guidelines seek to assist HSAs and other agencies in the identification of excess resources, a critical first step in encouraging more appropriate resource development and allocation of new resources. Further iterations will address problems of access and the more equitable distribution of health resources and the quality of care, as well as more long-range solutions to the inflation of health care costs. Although the initial issuance of the Guidelines focuses an acute care, these services and facilities should be viewed in terms of the full range of health care services, including those of ambulatory and long-term care.

As they are fully developed, the Guidelines will contain a statement of national health planning goals as well as resource standards. However, the initial issuance is limited to statements of resource standards with respect to specific categories of health services and facilities. Future iterations will encompass goals as well as resource standards.

Section 1513(b)(2) of the Public Health Service Act requires Health Systems Agencies, in the development of their Health Systems Plans, to give "appropriate consideration" to the recommended National Guidelines issued by the Secretary pursuant to section 1501. Health Systems Plans are also to "take into account" and "be consistent with" the Guidelines respecting the appropriate supply, distribution, and organization of health resources (section 1501(b)(1)).

The National Guidelines are to be considered by Health Systems Agencies as they assess the current conditions of the health care systems in their areas. Upon reviewing the relationship between current conditions and the Guidelines, agencies are expected to establish goals and set forth plans that are consistent with achieving the quantitative levels contained in the standards.

It should be noted that Health Systems Plans will be considered "consistent with" the Guidelines only where they establish goals and set forth plans not in excess of the level set forth in the Guidelines where that level is stated as a maximum, or not less than the level set forth in the Guidelines where that level is stated as a minimum, except where specific exceptions are provided in the Guidelines.

It is recognized that Health Systems Agencies are currently in the process of developing and establishing Health Systems Plans. The Secretary does not expect, and will not require as a condition of full designation of HSAs, consistency of Health Systems Plans with the National Guidelines until one year after the

date of publication of final regulations on the National Guidelines. All plans established by HSAs thereafter will be required to be consistent with the National Guidelines and will be reviewed by the Secretary on that basis. It is intended that Health Systems Plans establish goals and set forth plans designed to achieve the quantitative levels specified within five years. If an HSA area is able to achieve target levels in less than five years, it is urged to do so. HSAs are also urged to consider the Guidelines to the maximum extent possible in current planning efforts.

In view of the vast differences which exist among areas of the nation, local circumstances may render certain of the national standards inappropriate. Thus, the Guidelines provide for exceptions to the standards. Where a Health Systems Agency concludes that one or more of the standards should not apply to its area, it should set forth in its Health Systems Plan the basis for that conclusion. Such exceptions set forth in the HSP will be reviewed by the Department as part of the review of the performance of the plan development function by Health Systems Agencies.

The standards set forth below are intended to provide a basis for the identification of the inefficient use of scarce resources within the health sector. Many areas of the country have already achieved conditions more favorable than those specified in the National Guidelines. In those circumstances, it is not intended that HSAs plan for a level of resources in excess of that needed to adequately serve the needs of the community. Nor is it intended that HSAs refrain from planning with respect to health services and facilities which are not addressed in the Guidelines.

It should be noted that each State's Health Plan developed under Title XV of the Public Health Service Act must be made up of the Health Systems Plans for areas within the State, which in turn must take into account and be consistent with the National Guidelines Health Systems Plan also provide one of the bases for the development of the State Medical Facilities Plan required under Section 1603. Thus, it is expected that the National Guidelines will be reflected in the development of State Health Plans and State Medical Facilities Plans.

In addition, regulations issued concerning the certificate of need function (42 CFR Chapters 122 and 123) cite consistency with the Health Systems Plan for an area as one criterion for review of new institutional health service projects. Thus, it is anticipated that the National Guidelines will also be addressed in the criteria adopted by HSAs and SHPDAs governing review activities under certificate of need, the review of new institutional health services, and other mandated reviews.

The state of the art of establishing specific quantitative resource standards is still in its infancy. A vast range of factors are to be considered in the determination of the "appropriateness" of the supply, distribution, and organization of health resources. The standards set forth below will require periodic review and revision as knowledge is increased concerning the most appropriate configuration of resources to provide services which meet the health needs of the population with a minimum of duplication. The Guidelines will thus be reviewed at least every two years and revised as necessary based upon further analysis and experience with their use.

The resource standards for the nine categories of services and facilities included herein will be refined based upon the comments received and on the basis of further analysis. Additional work will also be undertaken to publish, for comment in the form of a subsequent Notice of Proposed Rulemaking, a statement of national health planning goals and additional resource standards.

Interested parties are invited to submit written comments on the National Guidelines for Health Planning by November 22, 1977. After consideration of the materials received in response to this Notice, the Secretary will make appropriate revisions and by regulation issue final Guidelines.

The proposed Guidelines set forth below will be the subject of discussion in public session at the meeting of the National Council on Health Planning and Development on September 23, 1977, at 2:00 P.M., in the Auditorium, HEW South Portal Building, 200 Independence Avenue SW., Washington, D.C.

It is therefore proposed to issue National Guidelines for Health Planning as set forth below.

Dated: September 12, 1977.

JULIUS B. RICHMOND,
Assistant Secretary for Health.

Approved: September 14, 1977.

HALE CHAMPION,
Acting Secretary.

It is proposed to add Part 121 to Title 42 of the Code of Federal Regulations which, when codified, will consist of the following material:

I. GENERAL HOSPITALS—BED-POPULATION RATIO

GUIDELINE

There should be less than four non-Federal, short-term hospital beds for 1000 persons in a health service area; except under extraordinary circumstances. The standard for the bed-population ratio applies to all non-Federal short-term hospital beds (including general medical/surgical, pediatric, obstetric, and other short-term specialized beds).

Conditions which justify an exception to this standard for a health service area are:

1. *Age correction:* Individuals 65 years and older have a higher hospital utilization rate—up to four times that of the general population—than any other age group. Bed-population ratios for health service areas in which the percentge of elderly people is significantly (more than 33 percent) higher than the national average may be planned at a level higher than 4.0 per 100 persons.

2. *Seasonal population fluctuations:* Large seasonal variations in hospital utilization may justify bed-population ratios higher than 4.0 per 1000 persons. Bed-population ratios should reflect the Nation's vacation and recreation patterns as well as the needs of migrant workers.

3. *Urban areas:* Large numbers of beds in one part of a Standard Metropolitan Statistical Area (SMSA) may be compensated for by fewer beds in other parts of the SMSA. Health service areas which include a part of an SMSA may plan for bed-population ratios higher than 4.0 per 1000 persons reflecting existing patterns if there is a joint plan among all the Health Systems Agencies serving the SMSA which provides for less than 4.0 beds per 1000 persons in the SMSA as a whole.

4. *Rural areas:* Hospital care should be accessible to most individuals within a reasonable period of time. In rural areas in which a majority of the residents would otherwise be more than 45 minutes automobile travel time from a hospital, a bed-population ratio of greater than 4.0 per 1000 persons may be justified.

5. *Areas with referral hospitals:* In the case of an institution which provides a substantial portion of its services to individuals not residing in the health service area in which the institution is located, the HSA for that area may exclude from its computation of bed-population ratio the patient load that is from outside the HSA.

DISCUSSION

There is general agreement that the number of general hospital beds in the United States is significantly in excess of what is actually needed. This excess bed capacity contributes to the high cost of hospital care with little or no recognizable health benefits. Empty beds are often filled by patients who could be cared for as well or better using less expensive treatment modalities, such as ambulatory care or home care.

In 1976, the Institute of Medicine recommended that the nation should achieve at least a 10 percent reduction in the bed population ratio in the next five years and further significant reductions thereafter. The Institute statement noted: This would mean a reduction from the current national average of approximately 4.4 non-federal short-term general hospital beds per 1,000 population to a national average of approximately 4.0 in five years and well below that in the years to follow; many states and health service areas should be below the national 4.0 average at the end of five years.

It must be stressed that the 4.0 beds per 1000 population standard is a maximum level and not a description of an ideal situation. It is anticipated that in subsequent plans HSAs will be required to indicate how they will reach a bed-population ratio of 3.7 per 1000 population except under extraordinary circumstances. HSAs whose areas are now below the 4.0 per 1000 level but above 3.7 per 1000 are urged to attempt to decrease bed-population ratios to the lower figure.

II. GENERAL HOSPITALS—OCCUPANCY RATE

GUIDELINES

There should be an average annual occupancy rate of at least 80 percent for all non-Federal, general short-term hospitals in a health service area, except under extraordinary circumstances. Conditions which justify an exception to this standard for a health service area include:

1. *Seasonal population fluctuations:* In some areas, the influx of people for vacation or other purposes may require a greater supply of hospital beds than would otherwise be needed. Large seasonal variations in hospital utilization which can be predicted through hospital and health insurance records may justify an average annual occupancy rate of lower than 80 percent.

2. *Rural areas:* Lower average annual occupancy rates are often required by small hospitals to maintain empty beds to accom-

modate normal fluctuations of admissions. In rural areas with significant numbers of small (fewer than 4,000 admissions per year) hospitals an average occupancy rate of less than 80 percent may be justified.

DISCUSSION

There is substantial evidence that excess hospital capacity contributes significantly to high hospital costs. Empty hospital beds are expensive to staff and maintain. Occupancy rates currently average 75 percent nationwide. Major hospital capacity studies indicate that an average hospital occupancy rate of 80 percent is a reasonable national goal. Higher averages have been advocated, especially for medical-surgical units. In 1973, the Hill-Burton program recommended a 90 percent average for medical-surgical units.

HSAs whose areas currently exceed the proposed 80 percent average annual occupancy rate should attempt to increase occupancy rates still further. It must be stressed that the proposed standards are minimal levels and not a description of an ideal.

III. OBSTETRICAL SERVICES

GUIDELINES

A. There should be at least 2000 deliveries annually in an obstetrical unit located in an SMSA with a population of 100,000 or more.

There should be at least 500 deliveries annually in any obstetrical unit not located in an SMSA with a population of 100,000 or more.

The exception to this standard is: In the case of an obstetrical unit serving an area in which travel time to the unit exceeds 45 minutes under normal driving conditions for 10 percent or more of the population, a lower number of deliveries in an obstetrical unit may be justified.

B. There should be an average annual occupancy rate of at least 75 percent in each obstetrical unit.

DISCUSSION

In view of declining birth rates and the mounting underutilization of obstetrical beds, obstetrical standards for the minimum number of deliveries and occupancy rates are designed to discourage unnecessary duplication and inappropriate proliferation of services, and to maintain quality of care.

The experience of many obstetrical departments indicates that more than 2000 deliveries are generally required to maintain a consistently high standard of ordinary obstetrical care and a reasonable economic operation. Thus, at least 2000 deliveries should occur annually in any maternity unit in an SMSA with a population of over 100,000. The long-term objective for very densely populated areas should be consolidation of maternity services to achieve 3,000-5,000 deliveries annually.

In keeping with the national priority set forth in Section 1502 of the Public Health Service Act for the consolidation and coordination of institutional health services, the consolidation of multiple, small obstetrical units with low occupancy rates should be undertaken where such action is not impeded by geographical barriers.

A unit that serves less than 2000 deliveries per year is needed to maintain accessibility to services when a facility is located in an area with a population of low density or geographic inaccessibility. Facilities not located in SMSAs of over 100,000 population should provide at least 500 deliveries annually. According to the American College of Obstetricians and Gynecologists, services of such a size are limited but adequate, and can provide care with reasonable efficiency. Below 500 deliveries, the quality of care and efficiency are decreased significantly.

Travel time may be used to determine whether obstetrical services would be made inaccessible to certain populations if the minimum volume standard for obstetrical units were to be applied. A travel time to obstetrical services in excess of 45 minutes under normal driving conditions for 10 percent or more of the population provides a basis for exception to the 500 minimum annual deliveries in sparsely populated areas.

IV. PEDIATRIC INPATIENT SERVICES—NUMBER OF BEDS

GUIDELINES

There should be a minimum of 20 beds in a pediatric unit. The exception to this standard is: In the case of a pediatric unit serving an area in which travel time to the unit exceeds 30 minutes under normal driving conditions for 10 percent or more of the population, a smaller size pediatric unit may be justified.

DISCUSSION

A pediatric inpatient unit is a specific section, ward, wing, or unit devoted primarily to the care of medical and surgical patients less than 15 years old, not including intensive care for infants less than 29 days old.

A pediatric unit should have a minimum of 20 beds. This standard is designed to insure that pediatric units are of an efficient and economical size. It has been recommended by various professional organizations and health planning agencies. Consolidation of pediatric care in units of at least twenty beds will promote the concentration of nursing and support staff with special pediatric knowledge and skills, the increased training of staff, and the provision of special treatment and other ancillary facilities which meet the special needs of children. The recent Report of the Committee on Implications of Declining Pediatric Hospitalization Rates of the National Research Council states that, "For a policy of housing children separately to be effective, certain minimum services and facilities are needed thus requiring bed capacity and utilization to make provisions for these services and facilities economically feasible."

The 30 minutes travel time criterion may be used to identify those locations in which consolidation of pediatric units may not provide for appropriate access. Close proximity to pediatric facilities is desirable to permit children to remain close to their homes and to allow for frequent visits by family and friends. Such visits are highly desirable and have been found to be an aid to improvement and cure.

V. PEDIATRIC INPATIENT SERVICES—OCCUPANCY RATES

GUIDELINE

Pediatric units should maintain average annual occupancy rates related to the number of pediatric beds (exclusive of neonatal intensive care units) in the facility. For a facility with 20–39 pediatric beds, the average annual occupancy rate should be at least 65 percent; for a facility with 40–79 pediatric beds, the average annual occupancy rate should be at least 75 percent; for facilities with 80 or more pediatric beds, the average annual occupancy rate should be at least 80 percent.

DISCUSSION

Variable occupancy rates are designed to reflect the need for smaller units to maintain the capacity to accommodate normal day-to-day fluctuations in admissions and to set aside pediatric beds for particular ages and types of cases. Such scheduling problems are less severe in pediatric units of a greater capacity. Moreover, large units are able to sustain higher occupancy rates because they are frequently associated with regional centers which serve patients needing types of care that can be scheduled on a more flexible basis.

VI. NEONATAL INTENSIVE CARE UNITS

GUIDELINES

A. The total number of neonatal intensive care beds should not exceed four per thousand live births per year in a defined neonatal service area.

B. A single neonatal intensive care unit should contain a minimum of 20 beds.

DISCUSSION

A Neonatal Intensive Care Unit (NICU) is a special unit staffed and equipped solely for the intensive care of newborns who are less than 29 days old. The term "bed" is used in a generic sense and includes isolettes or basinettes. Neonatal intensive care is a highly specialized service required by only a very small percentage of infants. It has been estimated that four neonatal intensive care beds per thousand live births are adequate to meet this need, taking into account the incidence of high-risk pregnances, the percentage of live births requiring intensive care and the average length of stay in neonatal intensive care units.

Since the minimum number of isolettes will serve the patient load resulting from a representative population cohort for approximately one million, perinatal centers will often be a resource of two or more HSAs. Thus, a defined neonatal service area should be identied by the relevant HSAs in conjunction with the State Agency.

No exception to this standard on the basis of travel time to the service is proposed, since high risk mothers often give birth at facilities which have an NICU, and infant transport and special communication systems are available in situations in which transfer of the infant to a different facility is necessary.

The American Academy of Pediatrics has noted that "the best care will be given to high risk and seriously ill neonates if intensive care units are developed in a few adequately qualified institutions within a community rather than within many hospitals. Properly conducted, early transfer of these infants to a qualified unit provides better care than do attempts to maintain them in inadequate units."[1] This regionalized approach is reflected in the minimum size standard which is designed to foster the location of neonatal intensive care units in medical centers which have available special consultative services, staff, equipment and facilities; and enhance the quality of care. The standard is also designed to promote efficiency of operation, which has been found to require neonatal intensive care units containing 20 or more beds.

VII. OPEN HEART SURGERY

GUIDELINES

A. There should be a minimum of 200 procedures performed annually in any institution in which open heart surgery is performed.

B. There should be no new open heart units opened unless each existing or previously approved unit in the health service area (or areas) to be served is operating and is expected to continue to operate at a minimum of 350 open heart surgery cases per year.

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[1] American Academy of Pediatrics, Commit on Hospital Care, Care of Children in Hospitals, 2nd Edition (Evanston, Illinois: American Academy of Pediatrics, 1971), p. 112.

DISCUSSION

Open heart surgery for congenital and acquired heart and coronary artery disease represents a marked advance in patient care. Highly specialized open heart procedures require very costly, highly specialized manpower and facility resources. Thus, every effort should be made to limit duplication and unnecessary expenditures for resources related to the performance of open heart procedures, while maintaining high quality of care.

Based upon recommendations by various professional organizations and health planning agencies, a minimum of 200 open heart surgery procedures should be performed annually to maintain quality of patient care and to minimize the unnecessary duplication of health resources. In order to prevent duplication of existing resources which may not be fully utilized, the opening of new open heart surgery units should be contingent upon existing units operating, and continuing to operate, at a level of at least 350 procedures per year. This represents the optimum number of procedures which can be performed by a single open heart surgery team while maintaining a high quality of care.

VIII. CARDIAC CATHETERIZATION UNIT SERVICES

GUIDELINES

A. There should be a minimum of 300 procedures (intracardiac and/or coronary artery catheterization) performed annually in any adult cardiac catheterization unit.

B. There should be a minimum of 150 cardiac catheterizations performed annually in any pediatric cardiac catheterization unit.

C. There should be no new cardiac catheterization units opened in any facility not performing open heart surgery.

D. There should be no new adult cardiac catheterization units opened unless the projected number of studies per year is greater than 500 based on the current number of procedures, existing capacity, estimated need and referral patterns in the health service area(s) to be served and as determined by the Health Systems Agency(ies).

DISCUSSION

The modern cardiac catheterization unit requires a highly skilled staff and expensive equipment. While some units with excellent quality and safety records perform fewer studies, it is generally recognized that a minimum of 300 procedures per year is necessary to maintain the skills of the catheterization team and the most effective and safe operation of the unit. The underutilized unit in addition represents a less efficient use of an expensive resource and frequently reflects unnecessary duplication of services in an area.

The patient studied in the cardiac catheterization unit is frequently recommended for open heart surgery. While acceptable inter-institutional referral patterns exist in many areas, optimally, cardiac catheterization units should be located within a facility in which cardiac surgery is performed. Consequently, new cardiac catheterization units should only be opened in conjunction with an existing or simultaneously opened open heart surgery program.

This standard is consistent with recommendations of several health planning agencies, the Joint Commission on Accreditation of Hospitals and the Inter-Society Commission on Heart Disease Resources.

IX. RADIATION THERAPY

GUIDELINES

A. A megavoltage radiation therapy unit should serve a population of at least 150,000 persons or at least 450 new cancer cases per year.

B. There should be no new megavoltage units opened unless each existing or approved megavoltage unit in the health service area(s) is performing and is expected to continue to perform at least 7,500 treatments per year.

DISCUSSION

Although various types of radiation are indicated and used for tumors with different characteristics, megavoltage equipment (2–50 megavolt) is accepted as the most efficacious for treatment of deep-seated tumors. Megavoltage equipment is expensive to purchase, install, and support on a continuing basis. Every effort should thus be made to avoid unnecessary duplication of this costly resource.

The three most common types of units which are used to deliver megavoltage therapy are cobalt 60, linear accelerator, and Betatrons. Each of these units can deliver 7,500 treatments per year.

Experience indicates that two-thirds of new cancer patients will require megavoltage radiation therapy, and each beginning patient will require approximately 25 treatments per year. The above standards are designed to provide the needed treatment capabilities while avoiding unnecessary duplication of radiation therapy units and under-utilization of existing capacity.

X. COMPUTED TOMOGRAPHIC SCANNERS

GUIDELINES

[2] "A Policy Statement: Computed Tomoner (head and body) should operate at a minimum of 2,500 patient procedures per year.

B. There should be no CT scanners approved unless each existing or approved CT scanner in the service area is performing at a rate greater than 4,000 patient procedures per year.

C. Charges for existing or proposed CT scanner are to be calculated on the basis of 2,500, the projected or actual number of patient procedures per year, whichever is greater.

D. There should be no new computed tomographic (CT) scanners approved unless the owners or operators of the proposed equipment will set in place, with operation of the equipment, a data collection system.

DISCUSSION

Because CT scanners are expensive to purchase, to maintain, and to staff, every effort must be made to contain costs while providing an acceptable level of service. Full and appropriate utilization of existing units will prevent needless duplication and limit unnecessary increases in health care costs.

Estimates of full utilization of CT scanners range from 1,800 to 4,000 patient procedures per year. Surveys of actual usage show a slightly wider range. The Institute of Medicine, provider organizations, and specialists who have carefully reviewed these data and analyzed the capabilities of various commercially available units have recommended that 2,500 patient procedures per year be considered as the minimal acceptable number for adequate utilization. Prior to opening more than one CT Scanner in a service area, existing clinical units should be operating at a maximum level.

A summary of the data collected on CT scanners should be submitted by the owners or operators to the appropriate HSA, to enable the Agency to adequately plan distribution and use of CT scanners in the area. The data to be collected should include the following: [3]

Presenting signs and symptoms of CT examinations.

Demographic characteristics of recipients of CT examinations.

Rate of positive diagnoses of different disease conditions by CT.

Place of CT examinations in sequence with other diagnostic procedures.

Sensitivity and specificity of CT examinations performed in different parts of the body.

XI. END-STAGE RENAL DISEASE (ESRD)

GUIDELINE

The Health Systems Plans established by health systems agencies should be consistent with standards and procedures contained in the DHEW regulations governing conditions for coverage of suppliers of end-stage renal disease services, 20 CFR Part 405, Subpart U.

DISCUSSION

The ESRD Program was created pursuant to Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603), which extends Medicare benefits to any individual who has end-stage renal disease requiring dialysis or transplantation, provided that such individual: (1) is fully or currently insured or entitled to monthly benefits under Title II of the Social Security Act; or (2) is the spouse or dependent child of an individual so insured or entitled to such monthly benefits. In order for an ESRD facility to qualify for reimbursement under the program, the facility must meet the conditions for coverage of suppliers of end-stage renal disease services as established by regulation. These conditions incorporate standards which relate to the supply, distribution, and organization of ESRD facilities. The standards were developed by the Department of Health, Education, and Welfare and were based on extensive consultation with professionals and other persons knowledgeable in the areas of nephrology and transplant surgery. Because these standards are already published as regulations, it was not deemed necessary to republish them here.

[FR Doc.77-27493 Filed 9-22-77;8:45 am]

[3] "A Policy Statement: Computed Tomographic Scanning," Institute of Medicine, National Academy of Sciences, Washington, D.C., April 1977.